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# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

Total Number of Pages in This Submission

| | |
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| Application Number | 09/544,004 |
| Filing Date | 04/06/2000 |
| First Named Inventor | Saebo et al. |
| Art Unit | 1617 |
| Examiner Name | S. Wang |
| Attorney Docket Number | CONLICO-04284 |

## ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
- [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
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- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
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- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):

Check in the amount of $500.00 - fee for filing a Brief in support of an appeal.

**Remarks**

Appellants' herewith file, in triplicate, Appellants' Brief. This Brief is in furtherance of the Notice of Appeal filed September 29, 2005.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | MEDLEN & CARROLL, LLP | | |
| Signature | | | |
| Printed name | J.Mitchell Jones | | |
| Date | November 29, 2005 | Reg. No. | 44,174 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

| | | | |
|---|---|---|---|
| Signature | | | |
| Typed or printed name | Mary Ellen Waite | Date | November 29, 2005 |

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Asgeir Saebo *et al.*
Serial No.: 09/544,004 Group No.: 1617
Filed: 04/06/2000 Examiner: S. Wang
Entitled: **CONJUGATED LINOLEIC ACID COMPOSITIONS**

# APPELLANTS' BRIEF

**APPEAL NO.:**

Mail Stop Appeal Brief - Patents
Commissioner for Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)**

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Appeal Brief - Patents , Commissioner for Patents and Trademarks P.O. Box 1450 Alexandria, VA 22313-1450

Dated: November 29, 2005 By: Mary Ellen Waite

Sir or Madam:

This Brief is in furtherance of the Notice of Appeal filed September 29, 2005.

The fees required under § 1.17(h) and any required Petition for Extension of Time for filing this Brief and fees therefore are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

**This Brief is transmitted in triplicate.** [37 C.F.R. § 41.37(c)].

12/06/2005 TBESHAH1 00000021 09544004
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This Brief contains these items under the following headings and in the order set forth below [37 C.F.R. § 41.37(c)]:

## I. REAL PARTY IN INTEREST

The real party in interest is Natural ASA, a Norwegian Corporation.

## II. RELATED APPEALS AND INTERFERENCES

A Decision On Appeal was mailed July 20, 2005, for Appeal No. 2005-0150 relating to U.S. Patent Application Serial No. 09/271,024, filed March 17, 1999. A copy of this Decision is provided in Section X. A Decision On Appeal was mailed August 30, 2005, for Appeal No. 2005-1578 relating to U.S. Patent Application Serial No. 09/132,593, filed August 11, 1998. A copy of this Decision is provided in Section X. A Notice Of Appeal was filed on July 9, 2004, for U.S. Patent Application Serial No. 09/949,458, filed September 7, 2001. There are no other related appeals or interferences known to Appellants, Appellants' legal representative, or the Assignee.

## III. STATUS OF CLAIMS

Claims 1 - 38 were filed in the original application. During prosecution of the application, Claims 6-9, 20-23, and 31-38 were cancelled, Claims 1, 5, 10, 12-15, 17-19, and 24-27 were amended, Claims 39 and 40 newly added, and Claim 40 subsequently canceled. Claims 1-5, 10-19, 24-30 and 39 have been rejected by the Office in the Final Office Action dated June 29, 2005 (Paper No. 26). Therefore, Claims 1-5, 10-19, 24-30 and 39 are pending in this appeal. No other claims are pending. Thus, Appellants appeal the Final Office Action of June 29, 2005 (Paper No. 26).

The Claims, as they now stand, are set forth in the Claims Appendix.

## IV. STATUS OF AMENDMENTS

Appellants' Response to the Office Action filed on April 12, 2005 (Paper No. 25), has been entered per the Final Office Action dated June 29, 2005 (Paper No. 26). The amendments to the claims made in the April 12, 2005, Office Action Response were acknowledged by the Examiner in the Final Office Action dated June 29, 2005 (Paper No. 26). Thus, there are no pending amendments not entered into the record.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to the field of human and animal nutrition, and in particular to certain novel compositions of conjugated linoleic acids (CLA). These compositions are prepared according to a novel method that controls oxidation of CLA into volatile organic compounds and in some cases contain antioxidants that control oxidation. Compositions comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator, wherein the free radical scavenger and the metal chelator are different compounds are described in, for example, the Specification at page 23, lines 16-27. Food products and food supplements comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator, wherein the free radical scavenger and the metal chelator are different compounds are described in, for example, in the Specification at page 23, lines 16-27. Such compositions, food products, and food supplements, wherein the isomerized conjugated linoleic acid moiety contains less than 100, 50, 10, or 5 parts per million total of volatile organic compounds are described in, for example, the Specification at page 5, lines 18-27, page 6, lines 7-16, page 6, line 29 through page 7, line 5. Such compositions, food products, and food supplements, wherein the isomerized conjugated linoleic

acid moiety is a free fatty acid, an alkyl ester, or a triacylglyceride are described in, for example, the Specification at page 5, line 28 through page 6, line 2, page 8, lines 16-18, and Examples 1, 5, 6, 10, 11, 14 and 15. Such compositions, food products, and food supplements, wherein the metal oxidant chelator is lecithin or ascorbic acid are described in, for example, the Specification at page 5, lines 6-10, page 23, lines 16-27, and page 26, lines 5-21. Such compositions, food products, and food supplements, wherein the volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof are described in, for example, the Specification at page 9, lines 10-15, and Example 12.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There is one ground of rejection to be reviewed on appeal:

Whether Claims 1-5, 10-19, 24-30 and 39 are obvious over both Cook et al. (U.S. Pat. No. 5,760,082) and Lievense (U.S. Patent No. 6,159,525) in view of Cain et al. (WO 97/18320), Remmereit (U.S. Patent No. 6,034,132) and Appellant's Disclosure.

## VII. ARGUMENT

### A. Issue 1 – Whether Claims 1-5, 10-19, 24-30 And 39 Are Obvious Under 35 U.S.C. §103(a)

#### 1. The Examiner Has Not Established A *Prima Facie* Case Of Obviousness

Claims 1-5, 10-19, 24-30 and 39 stand rejected under 35 U.S.C. §103(a), as allegedly obvious over both Cook et al. (U.S. Pat. No. 5,760,082) and Lievense (U.S. Patent No. 6,159,525) in view of Cain et al. (WO 97/18320), Remmereit (U.S. Patent No. 6,034,132) and Appellant's Disclosure. Required elements of independent Claims 1, 10, 15, 24 and 39 include

compositions, food products, or food supplements comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator. The Examiner fails to establish a *prima facie* case of obviousness because the cited references fail to teach all the elements of the claims.

It is well-established case law that a *prima facie* case of obviousness requires a reference or combination of references teach or suggest all of the elements of the claimed invention. *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990). Here, the Examiner admits that the Cook, Lievense, Cain and Remmereit references fail to teach compositions, food products, or food supplements comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator: "The primary references do not teach expressly the employment of a combination of antioxidant and metal (oxidant) chelator, such as ascorbic acid and lecithin, or the use of a commercial antioxidant product, Controx, or particularly point out the amount of VOC." Office Action dated June 29, 2005, page 3 (Paper No. 26). As such, the cited references do not teach all of the elements of Claims 1-5, 10-19, 24-30 and 39.

Despite not providing references that teach all of the elements of Claims 1-5, 10-19, 24-30 and 39, the Examiner cites *In re Kerkhoven*, 205 USPQ 1069 and argues, "As to the employ of two of the known antioxidants, note, it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in the prior art, thus, the claimed invention which is a combination of two known antioxidants sets forth prima facie obvious subject matter." Office Action dated June 29, 2005, page 4 (Paper No. 26).

The Examiner, however, is misapplying the *Kerkhoven* case. The claimed invention is not simply "a combination of two known antioxidants." It is the use of antioxidants and chelators to stabilize CLA – a compound that has proven to be particularly difficult to stabilize. Thus, the holding of *Kerkhoven* does not apply to the claimed invention, and does not remedy the Examiner's failure to provide references that teach all of the elements of the claimed invention. Indeed, this flaw is further highlighted by the Examiner's admission provided above that the prior art does not teach a combination of chelators and antioxidants to stabilize CLA. Absent such a description, Claims 1-5, 10-19, 24-30 and 39 cannot be obvious.

**2. The Claimed Invention Lies In The Discovery Of The Source Of A Problem Unrecognized In The Prior Art**

The Examiner has failed to consider the claimed invention in light of the fact that it lies in the discovery of the source of a problem unrecognized in the prior art. It is a well-established rule in patent law that "[i]t should not be necessary . . . to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified." (*In re Sponnable*, 405 F.2d 578, 585 (C.C.P.A. 1969); *In re Kosei Nomiya et al.*, 509 F.2d 566, 571 (C.C.P.A. 1975)). Prior to the claimed invention, a problem within the art was VOC (volatile organic compound) formation in CLA compositions. The Appellants recognized that the source of this problem was the susceptibility of CLA to breakdown in the presence of metal ions. In support of this argument, the Appellants submitted in the Office Action Response dated October 6, 2004 (Paper No. 22), the Declaration of Asgeir Sæbo, one of the inventors, provided at Section IX. As indicated in the Saebo Declaration, Natural ASA commissioned scientists at MATFORSK (the Norwegian Food Research Institute), to conduct tests on the stability of CLA compositions. As detailed in the Saebo Declaration, the

Applicants recognized the problem that the use of antioxidants such as ascorbic acid was insufficient to prevent the formation of undesirable products in CLA compositions. Applicants recognized that the source of this problem was CLA's susceptibility to breakdown in the presence of metal ions. (Specification, page 24, lines 20-25). This "source of the problem" had gone unrecognized in the prior art. It is no surprise that the prior art did not teach the combination of the claimed ingredients. Thus, according to the rule of *In re Sponnable*, the claimed invention is patentable even if the remedy was obvious once the source of the problem was identified. Indeed, the failure of the prior art to recognize or suggest a solution to the problem of VOC formation in CLA compositions strongly supports the patentability of the claimed invention.

In response to the Saebo Declaration, however, the Examiner argues that Applicants have made an "unexpected result" argument, that 37 C.F.R. §1.132 Declarations must compare the claimed subject matter with the closest prior art, and that the evidence must be commensurate in scope with the claimed invention. Office Action dated January 12, 2005, page 5-6 (Paper No. 24). The Examiner further argues, "It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated 'it is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.' The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan." Office Action dated June 29, 2005, pages 5-6 (Paper No. 26). The Examiner's arguments are misplaced.

The Saebo Declaration is not solely directed to evidence of unexpected results. Instead, the Saebo Declaration provides evidence supporting the facts that a) prior art methods of stabilization with just one compound such as ascorbic acid are insufficient (i.e., there is a problem); b) that applicant's solved the problem; and c) that the prior art compositions necessarily contained high levels of VOCs because the problem had not been solved. The Examiner's attempt to minimize the value of the Declaration as evidence because it is allegedly directed to unexpected results is misguided. Applicants note that the section of the MPEP upon which the Examiner relies (716.02(3)) is directly only to evidence of unexpected results, not to 1.132 Declarations in general. Because the Declaration is not solely directed to unexpected results, and instead contains other relevant, factual information, the Examiner must consider and give weight to the factual evidence contained in the Declaration instead of minimizing it. In any event, a comparison with the closest alleged prior art is provided because the control treatment in the experiments described in the Saebo Declaration utilizes ascorbic acid. Additionally, the Saebo Declaration is commensurate with the scope of the claims. The claims are directed in part to mixtures of free radical scavengers and metal chelators and the Declaration describes the use of precisely such compositions. Thus, the Saebo Declaration does directly support the claimed subject matter. Nothing more is needed or required by the law. Again, the Examiner has failed to address the factual evidence in the Saebo Declaration, and is attempting to avoid doing so through improper characterization. The claimed invention is non-obvious.

## VIII. CLAIMS APPENDIX

1. (Previously Presented) A composition comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator, wherein said free radical scavenger and said metal chelator are different compounds.

2. (Original) The composition of claim 1, wherein said isomerized conjugated linoleic acid moiety is a free fatty acid.

3. (Original) The composition of claim 1, wherein said isomerized conjugated linoleic acid moiety is an alkyl ester.

4. (Original) The composition of claim 1, wherein said isomerized conjugated linoleic acid moiety is a triacylglyceride.

5. (Previously Presented) The composition of claim 1, wherein said metal oxidant chelator is lecithin.

6 - 9. Canceled.

10. (Previously Presented) A food product comprising an isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator, wherein said free radical scavenger and said metal chelator are different compounds.

11. (Original) The food product of claim 10, wherein said moiety is selected from the group consisting of a triacylglyceride, a free fatty acid, and an alkyl ester.

12. (Previously Presented) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 50 parts per million total of volatile organic compounds.

13. (Previously Presented) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 10 parts per million total of volatile organic compounds.

14. (Previously Presented) The food product of claim 10, wherein said isomerized conjugated linoleic acid moiety contains less than 5 parts per million total of volatile organic compounds.

15. (Previously Presented) A food supplement comprising a isomerized conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator, wherein said free radical scavenger and said metal chelator are different compounds.

16. (Original) The food supplement of claim 15, wherein said moiety is selected from the group consisting of a triacylglyceride, a free fatty acid, and an alkyl ester.

17. (Previously Presented) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 50 parts per million total of volatile organic compounds.

18. (Previously Presented) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 10 parts per million total of volatile organic compounds.

19. (Previously Presented) The food supplement of claim 15, wherein said isomerized conjugated linoleic acid moiety contains less than 5 parts per million total of volatile organic compounds.

20-23. Canceled.

24. (Currently Amended) A food product comprising a conjugated linoleic acid moiety, at least one free radical scavenger, and at least one metal chelator, wherein said free radical scavenger and said metal chelator are different compounds, wherein said conjugated linoleic acid moiety contains less than 100 ppm volatile organic compounds.

25. (Previously Presented) The food product of Claim 24, wherein said metal oxidant chelator is selected from lecithin and ascorbic acid.

26. (Previously Presented) The food product of Claim 24, wherein said volatile organic compounds are selected from the group consisting of pentane, hexane, heptane, 2-butenal, ethanol, 3-methyl butanal, 4-methyl pentanone, hexanal, heptanal, 2-pental furan, octanol and combinations thereof.

27. (Previously Presented) The food product of Claim 24, wherein said conjugated linoleic acid moiety contains less than 5 ppm of said volatile organic compounds.

28. (Original) The food product of Claim 24, wherein said conjugated linoleic acid moiety is an ester of conjugated linoleic acid.

29. (Original) The food product of Claim 24, wherein said conjugated linoleic acid moiety is a triglyceride containing conjugated linoleic acid.

30. (Original) The food product of Claim 24, wherein said conjugated linoleic acid moiety is a free fatty acid.

31-38. (Cancelled).

39. (Previously Presented) A conjugated linoleic acid composition stabilized for storage comprising an isomerized conjugated linoleic acid moiety, said composition comprising at least one free radical scavenger, and at least one metal chelator, wherein said free radical

scavenger and said metal chelator are different compounds, and characterized in comprising at least 80 percent of isomers of conjugated linoleic acid.

40. (Cancelled).

## IX. EVIDENCE APPENDIX

A copy of the Saebo Declaration filed with the October 6, 2004 Office Action Response is provided with the present appeal brief.

## X. RELATED PROCEEDINGS APPENDIX

A copy of the Decision On Appeal mailed July 20, 2005, for Appeal No. 2005-0150 for U.S. Patent Application Serial Nos. 09/271,024, filed March 17, 1999, is provided with the present appeal brief.

A copy of the Decision On Appeal mailed August 30, 2005, for Appeal No. 2005-1578 for U.S. Patent Application Serial Nos. 09/132,593, filed August 11, 1998, is provided with the present appeal brief.

## XI. CONCLUSION

For the foregoing reasons, it is submitted that the Office's rejection of Claims 1-5, 10-19, 24-30, and 39 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: November 29, 2005

J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard St., Ste. 350
San Francisco, CA 94105
608/218-6900

*PATENT*
Attorney Docket No. **CONLINCO-04284**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | |
|---|---|---|---|
| In re Application of: | Asgeir Sæbo *et al.* | | |
| Serial No.: | 09/544,004 | Group No.: | 1617 |
| Filed: | 04/06/00 | Examiner: | Wang |
| Entitled: | **CONJUGATED LINOLEIC ACID COMPOSITIONS** | | |

# Declaration of Asgeir Sæbo

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

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Dated: 10/6/04 By: Mary Ellen Devlin

I, Asgeir Sæbø, state as follows:

1. My present position is R&D Manager, Vice President of Natural ASA.

2. I have reviewed the above captioned patent application, of which I am an inventor, the Office Action mailed April 7, 2004, and the Cook, Lievense, and Cain patents cited as prior art.

3. After review of the cited references, I conclude that the references do not teach or suggest the use of both metal chelators and peroxide scavengers to stabilize CLA.

4. Lipid oxidation is the result of many complex free radical reactions. Hydroperoxides are the primary oxidation products. According to the literature, hydroperoxides do not have any odor or flavor. However, hydroperoxides easily decompose to secondary oxidation products, of which some are volatile components with low sensory threshold values. These compounds may have a large impact on the sensory perception of oils or food products even in very low concentrations.

Highly unsaturated oils (e.g. fish oils and probably also CLA) may contain large amounts of volatile oxidation products even if the peroxide values are low. Thus, the oxidative status of such oils should not be assessed based on peroxide values alone. Scientists at MATFORSK (the Norwegian Food Research Institute), have analyzed volatile lipid oxidation products with various headspace/GC-MS techniques (personal communications). In their experience, this is undoubtedly one of the best techniques for assessment of the oxidative quality of fats, oils and foods. Data from such analyses generally correlates with sensory perception of rancidity.

5. Oils that are used in foods are mostly fully refined and deodorized. It is usually required that they have a neutral, bland odor and flavor with no hints of rancidity, i.e. they must have low levels of volatile oxidation products. Oil processing normally removes volatile oxidation products and other unwanted components, yielding oils with very low levels of volatile compounds. However, scientists at MATFORSK have analyzed CLA-products with regard to volatile oxidation products several times, and the results generally shows that CLA contains large amounts of volatiles compared to oils normally used in food production. Their recent experiments also indicate that CLA are very susceptible to oxidation when exposed to air and light.

6. At my request, scientists at MATFORSK (Norwegian Food Research Institute) conducted an experiment to analyze oxidation of CLA . A preparation of CLA was separated in 3 different samples. To sample A, a commercial mixture of antioxidants and metal chelators were added. A metal chelator was added to sample B and sample 3 was kept as reference sample. Samples were placed in a petri dish with air head space at 25C. Samples for analysis were withdrawn at 0, 24, and 48 hours. For analysis, a 3g aliquot of CLA together with an internal standard (ethylheptanate in soy bean oil) was measured into a flask and flushed with nitrogen (100 ml/min) for 15 minutes at room temperature to remove oxygen containing air. The closed vessel was thereafter placed in a water bath at 70C for 15 minutes. Volatile components that were released were trapped on adsorbent tube containing Tenax GR. Two parallels were run on each sample. The volatiles trapped were then desorbed at 250 C for 5 minutes in a Perkin Elmer ATD 400 and transferred to Agilent 6890 Gas Chromatograph with a Agilent 5973 MS Detector (El,70eV). Volatile components were separated on a DB-WAX coloumn from J&W Scientific,

0.25mm i.d.,0,5um, 30 m, with Helium 999.9999% as carrier. The temperature program was 30°C for 10 minutes and then 1°C $min^{-1}$ to 40°C, 3°C $min^{-1}$ to 70°C, and 6.5°C $min^{-1}$ to 230°C with a final holpup time of 5 minutes. Peak integrations and identifications were performed using a HP Chemstation (G1701CA version C.00.00, Agilent Technologies), Wiley 130K Mass Spectral Database (HP 61030A MS Chemstation, John Wiley and sons, Inc.) and NIST98 Mass Spectral Library med Windows Search Program (version 1.6d, US Secretary of Commerce, Gaithersburg, MD).

Upon sampling aliquots for analysis, the samples collected at 24 and 48 hours had a noticeably stronger smell than sample 1. This corresponds to the observed development of volatiles in the samples. The antioxidant mixture very strongly prevented the oxidation of CLA, whereas addition of a few ppm citric acid as metal chelator had only a minor effect. Measured as area count, the volatile heptanal was between 694 and 883 initially but amounted to 3605 and 14592 after 24 and 48 hours respectively if no antioxidant was added. Adding citric acid (normally only around 25 ppm is soluble in oil) reduced corresponding values to 3350 and 12701 and adding a commercial mixture containing metal chelators and other antioxidants reduced the values to 853 and 1131 respectively. The same pattern was observed for the volatiles hexanal, 2-octenal, 2-nonenal, 2.4-octadienal and several others. In conclusion, volatiles developed extremely fast in samples not containing a proper antioxidant mixture.

10. Based on above mentioned experiment and numerous reports earlier produced at Norwegian Food Research Institute, I asked for their opinion on feasibility of adding CLA oils to food items. Their response is added for reference at Tab 1.

11. I further declare that all statement made herein of my own knowledge are true and that all state nents made on information and belief are believed to be true; and further that these state nents were made with the knowledge that willful false statements and the like so made are puni hable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Asgeir Sæbø

Date: Oct. 5th. 2004

# OPPDRAGSRAPPORT

**MATFORSK** - Norsk institutt for næringsmiddelforskning

Osloveien 1, 1430 Ås
Tlf. 64 97 01 00

| **Rapportnummer:** |
|---|
| **O-7834-42**<br>**Preliminær** |
| **Tilgjengelighet:**<br>Fortrolig |

| **Rapportens tittel:** | **Dato:** |
|---|---|
| CLA i mat | 01.09.04 |
| **Prosjektleder/forfatter:** | **Prosjektleders signatur:** |
| Anne S. Jørgensen/Gjermund Vogt/Elisabeth Olsen | |
| **Avdelingsleder:** | **Avdelingsleders signatur:** |
| Ellen Merethe Magnus | |
| **Avdeling:** | **Prosjektnummer:** |
| Produkt og råvarekunnskap | O-7834 |
| **Oppdragsgiver:** | **Oppdragsgivers ref:** |
| Natural ASA | Asgeir Sæbø |

**Sammendrag/ekstrakt:**

We have been asked by Asgeir Sæbø, Natural ASA, to give our general opinion on use of CLA as an additive to foods. This statement refers to the oxidative stability of CLA only, and is based on our general knowledge of lipid oxidation. Health implications and other aspects of such use are not considered.

We have been asked by Natural ASA to give our general opinion on use of CLA as an additive to foods with regard to oxidative stability.

Scientists at MATFORSK, the Norwegian Food Research Institute, have worked with issues regarding oxidative stability of fats and oils for many years. Simple model systems as well as complex food products have been studied. We have participated in several projects with other institutes, e.g. "Optimal methods for analysis of rancidity in foods" and "Lipid quality and oxidation of polyunsaturated fatty acids in foods with marine lipids", and we often perform analyzes for the food industry. The following is based on our general knowledge and experience.

Lipid oxidation is the result of many complex free radical reactions. Hydroperoxides are the primary oxidation products. According to the literature, hydroperoxides do not have any odor or flavor. However, hydroperoxides easily decompose to secondary oxidation products, of which some are volatile components with low sensory threshold values. These compounds may have a large impact on the sensory perception of oils or food products even in very low concentrations. Highly unsaturated oils (e.g. fish oils and probably also CLA) may contain large amounts of volatile oxidation products even if the peroxide values are low. Thus, the oxidative status of such oils should not be assessed based on peroxide values alone. At MATFORSK, we have analyzed volatile lipid oxidation products with various headspace/GC-MS techniques for more than 10 years, and in our experience, this is undoubtedly one of the best techniques for assessment of the oxidative quality of fats, oils and foods. Data from such analyses generally correlates with sensory perception of rancidity.

Oils that are used in foods are mostly fully refined and deodorized. It is usually required that they have a neutral, bland odor and flavor with no hints of rancidity, i.e. they must have low levels of volatile oxidation products. Oil processing normally removes volatile oxidation products and other unwanted components, yielding oils with very low levels of volatile compounds. However, we have analyzed CLA-products with regard to volatile oxidation products several times, and the results generally shows that CLA contain large amounts of volatiles compared to oils normally used in food production. A recent experiment also indicates that CLA are very susceptible to oxidation when exposed to air and light. This leads to the assumption that use of CLA as an ingredient in food products may lead to deterioration of the product quality.

In our opinion, if CLA are to be utilized as an ingredient in food products, the oil needs to have a higher oxidative quality from the start and it must be stabilized against oxidation. Precautions against oxidation should be taken from start to finish in the production process for the oil as well as the food product. Such precautions could be addition of antioxidants as early as possible in the process, no exposure to air or light, and storage at as low temperatures as possible. We would also highly recommend thorough pre-trials to investigate the shelf life of the actual product under "normal" storage conditions before release.

# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASGEIR SAEBO, and CARL SKARIE



Appeal No. 2005-1578
Application No. 09/132,593

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-6 and 8, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A food product comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers.

The references relied upon by the examiner are:

| | | |
|---|---|---|
| Baltes et al. (Baltes) | 3,162,658 | Dec. 22, 1964 |

| | | |
|---|---|---|
| Cook et al. (Cook) | 5,554,646 | Sep. 10, 1996 |
| Cain et al. (Cain) | WO 97/18320 | May 22, 1997 |

Chin et al. (Chin), "Dietary Sources of Conjugated Dienoic Isomers of Linoleic Acid, a Newly Recognized Class of Anticarcinogens," J. Food Composition And Analysis, Vol. 5, pp. 185-197 (1992)

## GROUND OF REJECTION

Claims 1-6 and 8 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Cook, Cain, Chin and Baltes.

We reverse.

## DISCUSSION

According to the examiner (Answer, page 3), Cook "teach an active form of conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,11-octadecadienoic acid, which includes esters, salts and free acids of conjugated linoleic acid." In addition, the examiner finds (Answer, page 4), Cook teach that "[t]he conjugated linoleic acid may be obtained through isomerization of safflower oil;" "a food product comprising said active form of conjugated linoleic acid;" and that "[c]9, t11- and t10, c12-isomer[s] are the predominantly major isomers of the conjugated linoleic acid active form...." According to the examiner Cook do not teach 8,10- and 11,13-octadecadienoic acid isomers. Id. Therefore, the examiner reasons (id.), since Cook does not mention the 8,10- and 11,13-octadecadienoic acid isomers they must not be present and therefore, Cook meets appellants' claimed requirement of less than 2 percent 8,10- and 11,13-octadecadienoic acid isomers.

Regarding Chin and Cain, the examiner finds (id.), Chin "teach that it is known that c9;t11-conjugated linoleic acid isomer is an active form of conjugated linoleic acid," and that Cain "teaches a CLA [(conjugated linoleic acid)] composition made from sunflower oil for food additive contains 48.9% of c9, t11, 51.1% of t10,c12 linoleic acid or their esters."

Based on this evidence the examiner concludes (Answer, page 5),

> it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed ... invention was made, to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9, t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 1,13-octadecadienoic ester, such as those disclosed by Cain et al., and employ the mixture in food products.

In response, appellants argue (Brief, page 6), the Sæbo Declaration establishes that the compositions of Cook and Cain "cannot produce alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers." According to the Sæbo Declaration (received December 9, 2004), repeat experiments were performed using the methodology described in Cook and Cain. For Cook, the Sæbo Declaration reports (paragraph 4),

> this conjugation method resulted in in [sic] a conjugated linoleic acid composition comprising approximately 1.58% c11,t13 CLA and 2.34% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

Accordingly, the trans,trans isomers resulting from Cook's conjugation method are outside the requirements of appellants' claimed invention, which requires, inter alia, less than two percent trans, trans isomers.

Regarding Cain, the Sæbo Declaration reports (paragraph 6)

> this conjugation method resulted in a conjugated linoleic acid composition comprising approximately 3.49% c11,t13 CLA and 2.24% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

Accordingly, the trans,trans isomers resulting from Cain's conjugation method are outside the requirements of appellants' claimed invention, which requires, inter alia, less than two percent trans, trans isomers.

In response, the examiner asserts (Answer, page 6), "the declaration fails to establish the fact that the conjugated linoleic acid disclosed by Cook or Cain as recited in the prior office action contains more than 2% of the isomers identified in claim 1 herein." In support of this assertion, the examiner finds (Answer, bridging paragraph, pages 6-7), while Cain acknowledges the existence of trans,trans isomers, Cain "do not disclose the presence of trans isomers in their CLA composition." Apparently, the examiner is of the opinion that since Cain and Cook do not specifically state that their CLA compositions contain isomers other than t10,c12- and c9,t11-octadecadienoic acid, the CLA compositions taught by Cain and Cook only contain t10,c12- and c9,t11-octadecadienoic acid. We are not persuaded by the examiner's assertion.

According to Cook (column 1, lines 65 to column 2, line 3);

> [I]n one preferred embodiment of the method of the present invention the safe and effective amount of conjugated linoleic acid, which is selected from 9,11-octadecadienoic acid; 10,12-octadecadienoic acid; mixtures thereof; and non-toxic salts thereof is added to the feed of an animal in which it is desired to reduce the body fat.

We note, however, that according to Cook (column 4, lines 22-24, emphasis added), "[t]he terms 'conjugated linoleic acids' and 'CLA' as used herein are intended to include 9,11-octadecadienoic acid, [and] 10,12-octadecadienoic acid...." Thus, while Cook emphasizes the 9,11- and 10,12-octadecadienoic acid isomers, Cook leaves his definition of CLA open to "include" other isomers. In addition, Cook does not distinguish which geometric isomer is intended by the recitation of 9,11-octadecadienoic acid and 10,12-octadecadienoic acid. In this regard, we note that there is no requirement in Cook's claims that a particular CLA, let alone a particular geometric isomer of 9,11- or 10,12-octadecadienoic acid is required. Further, while the examiner recognizes (Answer, page 4), Cook discloses that "[c]9,t11- and t10,c12-isomer[s] are the predominantly major isomers of the conjugated linoleic acid...", the examiner fails to appreciate that Cook discloses (column 4, lines 48-50), "8 possible geometric isomers of 9,11 and 10,12-octadecadienoic acid (c9,c11; c9,t11; t9,c11; t9,t11; c10,c12; c10,t12; t10,c12 and t10,t12)...", all of which fall within Cook's definition of CLA. Accordingly, we fail to understand how the examiner has read Cook's disclosure as limited to a composition containing only the c9,t11- and t10,c12-isomers of octadecadienoic acid.

According to Cook (column 4, lines 28-29), "[t]he preferred method of synthesizing CLA is that described in Example 1", which appears in Column 2 of Cook. According to the Sæbo Declaration, in the repeat of Cook, "the conjugation conditions were the same as those described in [c]olumn 2 of ... [Cook]." The results reported in the Sæbo Declaration are consistent with Cook in that a CLA composition was obtained that included the 9,11 and 10,12 isomers of octadecadienoic acid. Cf. Cook, column 4, lines 22-24, emphasis added), "[t]he terms 'conjugated linoleic acids' and 'CLA' as used herein are intended to include 9,11-octadecadienoic acid, [and] 10,12-octadecadienoic acid...." While the results reported in the Sæbo Declaration are consistent with the disclosure of Cook, they are inconsistent with the requirements of appellants' claimed invention, because they include more than 2% of the trans,trans octadecadienoic acid isomer. Specifically, the resulting CLA composition contains, inter alia, 2.34% t9,t11 and t10,t12 CLA. For the foregoing reasons we are not persuaded by the examiner's assertions regarding Cook.

Regarding Cain, the reference discloses (page 3), "our invention concerns a new process for the preparation of CLA's, wherein the ratio $\frac{cis^{9}\text{-}trans^{11}}{trans^{10}\text{-}cis^{12}}$ can be chosen freely." Therefore, contrary to the examiner's assertion (Answer, page 7), it is not unreasonable for Cain to not report on the presence of other isomers in his CLA compositions, isomers other than $cis^{9}$-$trans^{11}$ and $trans^{10}$-$cis^{12}$ were simply not the focus of his invention. Cf. Sæbo Declaration, paragraph 7, "Cain may have simply chosen not to include non-

active isomers when reporting their results." In this regard, we note that Cain state (page 5), "our invention also concerns novel organic materials, ... wherein the conjugated polyunsaturated fatty acid moieties at least comprise two isomers $L_1$ and $L_2$ ...." According to Cain (id.), "is it preferred that $L_1$ and $L_2$ are $cis^{9}$ $trans^{11}$ and $trans^{10}$ $cis^{12}$-linoleic acid (or vice versa)[.]" See also, for example, claims 1, 6 and 9 of Cain, wherein similar language is used.

Therefore, similar to the facts in Cook, while Cain emphasizes the $cis^{9}$ $trans^{11}$ and $trans^{10}$ $cis^{12}$ isomers, Cain's compositions may comprise other CLA isomers. Accordingly, we see nothing inconsistent with the results of the repeat of Cain's methodology as presented in the Sæbo Declaration. Paragraph 6 of the Sæbo Declaration, and the results attached at Tab 2 of the Declaration, reports that Cains' methodology results in a composition comprising at least two isomers, the $cis^{9}$ $trans^{11}$ and $trans^{10}$ $cis^{12}$ isomers. The results also demonstrate however, that other isomers are also present in the resulting composition. Specifically, the resulting CLA composition contains, inter alia, 2.24% t9,t11 and t10,t12 CLA. For the foregoing reasons we are not persuaded by the examiner's assertions regarding Cain.

On reflection, we disagree with the examiner's conclusion (Answer, page 5), that it would have been prima facie obvious to a person of ordinary skill in the art, at the time the invention was made to combine the teachings of Cain, Cook and Chin[1] in the manner necessary to arrive at appellants' claimed invention.

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[1] In our opinion, the examiner's reliance (Answer, page 4) on Chin to teach that c9,t11-conjugated linoleic acid isomer is an active form of conjugated linoleic acid, is insufficient to make up for the deficiency in the combination of Cain and Cook.

We also note the examiner's reliance on Baltes (Answer, page 5), to "teach that employment of low alkali alcoholate as catalysts for isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers is known." However, in our opinion, Baltes fails to make up for the deficiency in the combination of Cain and Cook.

Prima facie obviousness based on a combination of references requires that the prior art provide "a reason, suggestion, or motivation to lead an inventor to combine those references." Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

> [E]vidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. . . . The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted). The suggestion to combine prior art references must come from the cited references, not from the application's disclosure. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Based on the foregoing, it is our opinion that the examiner failed to meet his burden of presenting the evidence necessary to support a prima facie case of obviousness. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, we reverse the rejection of claims 1-6 and 8 under 35 U.S.C. § 103 as being unpatentable over the combination of Cook, Cain, Chin and Baltes.

REVERSED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

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# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASGEIR SAEBO, CARL SKARIE, DARIA JEROME, and GUDMUNDER HAROLDSSON

Appeal No. 2005-0150
Application No. 09/271,024

HEARD: June 7, 2005



Before WILLIAM F. SMITH, ADAMS and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

## DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 5-8 and 13-17, which are all the claims pending in the application.[1]

Claims 5 and 13 are illustrative of the subject matter on appeal and are reproduced below:

5. A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R1, R2, and R3 attached at the positions of the OH-

[1] While the examiner states (Answer, page 2), "[t]he statement of the status of the claims contained in the brief is correct," we note that appellants' Brief does not address the status of claim 12. For clarity, we note that appellants cancelled claim 12, along with claims 1-4 and 9-11 in the amendment (see page 1) received November 14, 2000.

groups of a glycerol backbone, and wherein R1, R2 and R3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R1, R2 and R3, wherein said percentages are peak area percentages as determined by gas chromatography.

13. A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R1, R2, and R3 attached at the positions of the OH-groups of a glycerol backbone, and wherein R1, R2 and R3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R1, R2 and R3, wherein said percentages are peak area percentages as determined by gas chromatography.

The references relied upon by the examiner are:

| | | |
|---|---|---|
| Pariza et al. (Pariza) | 5,017,614 | May 21, 1991 |
| Nilsen et al. (Nilsen) | 5,885,594 | Mar. 23, 1999 |
| Cain et al. (Cain) | WO 97/18320 | May 22, 1997 |

## GROUNDS OF REJECTION

Claims 5-8 stand rejected under 35 U.S.C. 102(a) as anticipated by Cain.

Claims 13-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cain.

Claims 5-8 and 13-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Nilsen in view of Cain and Pariza.

We reverse.

## DISCUSSION

According to the examiner (Answer, page 3), the basis for each rejection is "fully set forth in prior office action, paper No. 26, mailed March 26, 2003." However, upon inspection of the Office Action mailed March 26, 2003 (see page 2), we find that instead of providing a statement of the rejection, the examiner refers to the "reasons set forth in the prior office action." It is in the Office Action mailed August 13, 2002 where we find a statement of each rejection on this record. We remind the examiner, as set forth in § 1208(A) of the Manual of Patent Examining Procedure

> Examiners may incorporate in the answer their statement of the grounds of rejection merely by reference to the final rejection (or a single other action on which it is based, MPEP § 706.07). Only those statements of grounds of rejection appearing in a single prior action may be incorporated by reference. An examiner's answer should not refer, either directly or indirectly, to more than one prior Office action. Statements of grounds of rejection appearing in actions other than the aforementioned single prior action should be quoted in the answer.

THE REJECTION UNDER 35 U.S.C. § 102:

According to the examiner (page 3, Office Action, mailed August 13, 2002),

> Cain teaches [example 6] an acyglycerol composition comprising mono-[,] di-[,] and tri-glyceride[s] wherein the fatty acid[s] are c9,t11 CLA[2] or t10, c12 CLA, wherein the total CLA in the composition is about ... [61.9%], of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer. No other CLA isomers are indicated, or suggested to be present in the composition.

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[2] According to Cain (page 1), CLA refers to compositions containing free conjugated linoleic acid. Cf. appellants' specification (page 9), "[a]s used herein, 'conjugated linoleic acid' or 'CLA' refers to any conjugated linoleic acid or octadecadienoic free fatty acid."

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Upon review of Cain we agree with the examiner that example 6 of Cain teaches a composition comprising "61.9% of conjugated linoleic acid (CLA) of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." In addition, we agree with the examiner that Cain is silent regarding the presence of other CLA isomers that may be present in the composition. Thus, the composition taught by Cain appears, in the first instance, to meet all the limitations of appellants' claimed invention. Accordingly, we find that the examiner has established a sufficient evidentiary basis to shift the burden to appellants to demonstrate that Cain does not anticipate their claimed invention. In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) ("when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."). In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971).

In response, appellants assert (Brief, page 5), Cain "does not anticipate [c]laim[s] 5-8 because the methods utilized by Cain et al. cannot produce the claimed CLA isomer profile (i.e., a CLA composition containing less than 1%

total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid isomers)." In support of this assertion, appellants direct our attention to the Saebo Declaration, which according to appellants "establishes that the compositions of Cain et al. necessarily include the 8,10 and 11,13 isomers of CLA." According to the Saebo Declaration (paragraph 4),

> In the repeat of Cain, the conjugation conditions were the same as those described in Example 6 of WO97/18320. The results of the conjugation reactions were analyzed by GC-MS. ... [T]his conjugation method resulted in a conjugated linoleic acid composition comprising approximately 3.49% c11,t13 CLA and 2.24% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

From this, appellants assert (Brief, page 8), "[a]pplicants followed the exact instructions of Cain and analyzed the product. The [a]pplicants did not fail to obtain CLA. Indeed, they obtained CLA with the isomers described by Cain et al. However, the fact remains that the CLA also contained other isomers that are not mentioned by Cain." According to appellants (Brief, bridging paragraph, pages 8-9), Cain's "silence concerning the presence of the isomers cannot be equated with the absence of the isomers. ... [Cain] does not specifically define CLA to include non-active CLA isomers." On this point the Saebo Declaration states (paragraph 5),

> [t]he [e]xaminer states ... that Cain teaches CLA compositions that are composed of 48.9% c9,t11 and 51.1% t10,c12 CLA, and that the analysis was carried out with gas chromatography and no other isomer of conjugated linoleic acid is detected. However, this does not mean that the other isomers were not present, as was found in my repeat of Cain. This discrepancy is explainable by the facts that 1) methods for the analysis of CLA compositions in 1996 were rather crude and 2)

> Cain may have simply chosen not to include non-active isomers when reporting their results.

In addition, appellants direct our attention to Sugano[3]. Brief, bridging paragraph, pages 10-11.[4] According to appellants (id.), Sugano "isomerized linoleic acid [under] conditions similar to those described by Cain...." However, as appellants explain (id.), in contrast to the results reported by Cain, Sugano's "resulting CLA preparation contained the following CLA isomers: 29.8% c9,t11/t9,c12; 1.3% c9,c11; 1.4%c10, c12; 18.6% t9,t11/t10,t12; 5.6% linoleic acid; and 13.7% other isomers." In view of the foregoing, appellants assert (Brief, page 11), "[i]n contrast to the simplified analysis presented in Cain et al., isomerization of CLA results in the production of many different isomers, not just the desired c9,t11 and t10,c12 isomers."

Appellants also direct out attention (Brief, page 11), to examples 1-4 of their specification in further support of their position that the methodology taught by Cain would have resulted in the production of CLA compositions that do not meet the limitations of their claimed invention. According to appellants (id., emphasis removed),

> [t]hese examples compare non-aqueous alkali isomerization under high or low temperatures and aqueous alkali isomerization under high or low temperatures. The important fact to note is that

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[3] Sugano et al. (Sugano), "Conjugated Linoleic Acid Modulates Tissue Levels of Chemical Mediators and Immunoglobulins in Rats," Lipids, Vol. 33, No. 5, pp. 521-527 (1998).

[4] Appellants also direct out attention to "Chapter 5 of the book Advances in Conjugated Linoleic Acid Research, Volume 2, J. Sebedio, W.W. Christie, and R. Adolf, Eds., AOCS Press, Champaign, IL, 2002...." See Brief, bridging sentence, pages 9-10. This reference, however, was published after appellants' March 17, 1999 filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. See In re Gunn, 537 F.2d 1123, 1128, 190 USPQ 402, 405 (CCPA 1976). Accordingly, we have not considered this reference.

> each reaction, even the low temperature non-aqueous alkali isomerization reaction (Example 1, Table 6), produced a distribution of the expected isomers, not just the c9,t11 and t10,c12 isomers.

From this appellants assert (id., emphasis removed), "the compositions of Cain necessarily contained levels [of] 8,10; 11,13; and trans,trans isomers that do not meet the[ir] claimed levels."

In response, the examiner appears to back away from his original finding (page 3, Office Action, mailed August 13, 2002) that "[n]o other CLA isomers are indicated, or suggested to be present in the composition" taught by Cain. In response to appellants' arguments, and contrary to his original inference, the examiner asserts (Answer, page 4), "nowhere in Cain states that 'conjugated linoleic acid' are exclusively for c9, t11; and t10, c12 isomers." Thus, the examiner appears to concede that the CLA compositions taught by Cain would be expected to contain additional CLA isomers other than the c9, t11; and t10, c12 isomers identified by Cain.

The examiner maintains, however, "there is no convincing evidence showing that Cain's composition has the amount of the particular isomers herein claimed." Apparently the examiner is referring to the requirement of appellants' claimed invention that the acylglycerol composition comprise "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions $R_1$, $R_2$ and $R_3$ ...." While the examiner appreciates that the composition taught by Cain would contain CLA isomers other than t10,c12 and c9,t11 octadecadienoic acid, the examiner makes no

attempt to explain why the compositions taught by Cain would necessarily contain "less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions $R_1$, $R_2$ and $R_3$ ..." as required by appellants' claimed invention. The only evidence on this record that addresses this point is appellants'. As discussed above, both the Saebo Declaration (using the same methodology as set forth in Cain), and the Sugano reference (using a similar methodology as set forth in Cain), resulted in a CLA composition that contained more than "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions $R_1$, $R_2$ and $R_3$ ...." In our opinion, the evidence of record weighs in favor of appellants, and rebuts the examiner's prima facie case of anticipation.

Accordingly, we reverse the rejection of claims 5-8 under 35 U.S.C. § 102(a) as anticipated by Cain.

THE REJECTIONS UNDER 35 U.S.C. § 103:

Cain:

According to the examiner (page 3, Office Action, mailed August 13, 2002), "Cain teaches an acylglycerol composition comprising mono-[,] di-[,] and tri-glyceride[s] wherein the fatty acids are c9,t11 CLA or t10, c12 CLA, no other CLA isomers are indicated, or suggested to be present in the composition. See, example[s] 6-10 at page[s] 16-22." The examiner finds that Cain characterize

> all the fatty acid[s] through gas chromatography and ... identified the CLA. For example, in example 6, ... [Cain] state[s] "[t]he fatty

> acid composition of the product, as determined by FAME GC, contained 63.8% CLA, of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." See page 16, lines 17-21.

From this the examiner asserts (id.), "the rest of the fatty acids are not CLA, and the CLA is composed entirely of cis 9, trans 11[ ]isomer and trans 10, cis 12 isomer."

In addition, the examiner finds (Answer, bridging paragraph, pages 3-4) that Cain teaches the use of the acylglycerol composition "in various food products including ice cream, soup, and bakery products. See, particularly, examples 12-17 at page 24-35 and the claims." The examiner recognizes, however, that Cain does not teach "that each of the isomers must be 30% or more of the total CLA moieties for the particular food products." Answer, page 4. Nevertheless, the examiner asserts (id.),

> it would be obvious to employ such [a] CLA composition in the food product, since such [a] CLA composition [comprising 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer] has been expressly disclosed by Cain [for use in a food product]. See, ... example 6.

In response, appellants assert (Brief, page 12), "[a]s established above [with regard to the rejection under 35 U.S.C. 102(a)], the compositions of Cain necessarily contain levels [of] 8,10; 11,13; and trans,trans isomers that do not meet the claimed levels. Thus, Cain et al. does not render the claims obvious." Similarly, the examiner relies on his response to the anticipation rejection. See Answer, page 6.

Accordingly, for the reasons set forth above, we find that the evidence of record weighs in favor of appellants. Therefore, the rejection of claims 13-17 under 35 U.S.C. § 103 as being unpatentable over Cain is reversed.

Nilsen in view of Cain and Pariza:

According to the examiner (page 4, Office Action, mailed August 13, 2002), Nilsen "teach a composition comprising 90-100[]% of an acylglycerol compound wherein the fatty acid radical is a conjugated polyunsaturated fatty acid." In this regard, the examiner finds (id.), "[t]he preferred conjugated polyunsaturated fatty acid is conjugated linoleic acid which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid." The examiner recognizes, however, that Nilsen does not teach "the employment of the combination of c9, t11-octadecadienoic acid and/or t10, c12-octadecadienoic acid in the acylglycerol, or the specific amounts of each of the two isomers...."

The examiner relies on Cain to make up for Nilsen's deficiency regarding the specific c9, t11, and t10, c12 isomers of octadecadienoic acid in the acylglycerol taught by Nilsen. According to the examiner (page 5, Office Action, mailed August 13, 2002), Cain "teach[es] that both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid are considered the active isomers of CLA, and are known to be beneficial for animal health." In this regard, the examiner relies on Pariza (id.), "to show that [a] person of ordinary skill in the art possess the skill of preparing/or isolating the pure single isomer employed herein. See,

particularly, column 4, line 50, bridging column 8, lines 68, wherein, the separation, purification, and analysis of the isomers are discussed."

To make up for Nilsen's failure to teach an acylglycerol composition containing at least approximately 30% c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, the examiner asserts (id.), "[t]he optimization of the ratio of the compounds is considered within the skill of the artisan."

Based on this evidence, the examiner finds (id.),

> it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed ... invention was made, to make the composition of Nilsen et al. with acyglycerol [sic] compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid and employ the composition in feed for animals.

In this regard, the examiner asserts (id.), Nilsen did "not use ... other isomers of conjugated linoleic acids.... Therefore[, Nilsen] meet[s] the limitation set forth in claim 5 that other isomers are present in amounts less than 1%...."

In response, appellants assert (Brief, page 13), Cain "does not teach compositions comprising less than 1% 8,10; 11,13; and trans-trans isomers or methods of obtaining such compositions." Regarding Nilsen, appellants assert (id., emphasis removed), like Cain, Nilsen "provides no such compositions or methods [nor does Nilsen] teach any method at all for conjugation, they merely list CLA in a long list of fatty acids that may be useful in their invention." In support of this assertion, appellants rely on paragraph 6 of the Saebo Declaration which states "[w]ith respect to the Nilsen reference, I note that it does not provide any method of producing conjugated linoleic acid having less

than 1% 8,10; 11,13; and trans-trans isomers." Regarding Pariza, appellants assert (Brief, bridging paragraph, pages 13-14), "does not teach preparation of CLA in amounts suitable for incorporation into acylglycerides. Indeed, the HPLC purified isomers are produced for use as chromatography standards. Importantly, because the isomers are produced for use as standards, Pariza does not teach or suggest combining the isomers to form a composition containing both t10,c12 and t9,c11 isomers are required by the [c]laims." See also Saebo Declaration, paragraph 7. Accordingly, appellants assert (Brief, page 14), Pariza "teaches away from a combination of isomers as required by the [c]laims."

In response, the examiner addresses each reference individually. Accordingly, we will address the examiner's discussion of each reference in turn.

Cain:

The examiner relies (Answer, page 8) on his response to the anticipation rejection to address appellants' assertions regarding Cain. Accordingly, for the reasons set forth above, we are not persuaded by the examiner's assertion.

Nilsen:

Regarding Nilsen, the examiner asserts (id.), "one of ordinary skill in the art would have been expected to be able to practice the invention claimed by Nielsen [sic], including making an acylglycerol compound wherein the Rs are conjugated linoleic acids (specifically defined as c9, t11; t10, c12 isomers), see the claims in Nielsen [sic] et al." We fail to see the relevance of the examiner's reference to the claims of Nilsen. Upon consideration of Nilsen's claimed

invention we find no specific reference to c9, t11; t10, c12 isomers of CLA. At best, Nilsen's claims relate to a genus of CLA isomers. In this regard, we note the examiner's reference (Answer, page 6, emphasis added), to column 4, lines 4-6 of Nilsen, for what the examiner believes to be Nilsen's disclosure of "[t]he preferred conjugated polyunsaturated fatty acid ... which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid." Appellants' claimed invention is directed to, inter alia, an acylglycerol composition containing at least approximately 30% t10, c12 octadecadienoic acid, not c10, t12-octadecadienoic acid. The examiner identifies no section of Nilsen, and we find none, that would suggest appellants' specific acylglycerol composition. Further, the examiner offers to response to appellants' assertion that Nilsen provides no method through which to produce an acylglycerol composition as set forth in appellants' claimed invention. Accordingly, we are not persuaded by the examiner's assertions to the contrary.

Pariza:

In response to appellants' argument concerning Pariza, the examiner asserts (Answer, page 8), "[a]ppellants concede[] that Paris [sic] et al. does provide purified CLA isomers, but nevertheless argue that Pariza's disclosure is for producing standard samples for HPLC, and is not in a scale suitable for making acylglycerol herein claimed." To this the examiner asserts (id.), "there is no limitation as to the quantity of the composition in claims 5-8." On reflection, we are not persuaded by the examiner's assertions.

While appellants do not dispute that Pariza teaches methods of making t10, c12 and c9, t11 octadecadienoic acid, appellants assert (Brief, page 13), "Pariza does not teach preparation of CLA in amounts suitable for incorporation into acylglycerides. Indeed, the HPLC purified isomers are produced for use as chromatography standards." In response, the examiner does not dispute that amount of t10, c12 and c9, t11 octadecadienoic acid produced in the method of Pariza would not be sufficient to produce appellants' claimed acylglycerol composition. Instead, the examiner concludes (Answer, page 8), "preparative HPLC would be obvious to one of ordinary skill in the art with similar condition[s]." Apparently, it is the examiner's position that a person of ordinary skill in the art would have found it obvious to scale-up the method taught by Pariza to produce a sufficient amount of t10, c12 and c9, t11 octadecadienoic acid to incorporate into acylglycerol molecules. The evidence of record, however, does not support the examiner's assertion. Further, the examiner fails to provide any evidence that the method taught by Pariza could be effectively scaled-up to produce the acylglycerol molecules required by appellants' claimed invention. In the absence of a reasonable expectation of success one is left with only an "obvious to try" situation which is not the standard of obviousness under 35 U.S.C. § 103. See In re O'Farrell, 858 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

In order to establish a prima facie case of obviousness, there must be more than the demonstrated existence of all of the components of the claimed subject matter. There must be some reason, suggestion, or motivation found in

the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). On the record before us, we find no reasonable suggestion for combining the teachings of the references relied upon by the examiner in a manner which would have reasonably led one of ordinary skill in this art to arrive at the claimed invention. The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In our opinion, the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness.

Accordingly, we reverse the rejection of claims 5-8 and 13-17 under 35 U.S.C. § 103 as being unpatentable over Nilsen in view of Cain and Pariza.

REVERSED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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